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EXAMINER	
PAGANO, ALEXANDER R	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
09/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com
PatentDocket@mofo.com
Drcaldwell@mofo.com

Office Action Summary	Application No.	Applicant(s)	
	10/579,253	WUNBERG ET AL.	
	Examiner	Art Unit	
	ALEXANDER R. PAGANO	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-4,6-10 and 12* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *1-4,9 and 10* is/are allowed.

7)☒ Claim(s) *6-8 and 12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/20/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 6-10 and 12 are pending in this Application and are currently under examination.

In response to Applicant's Reply (dated Sep. 7, 2011, the "Reply") to the Non-Final Rejection (notification date Jun. 09, 2011), the following applies.

Withdrawal of Claim Rejections - 35 USC § 112

Objection to claims 5-12 under 37 CFR § 1.75(c) as improper multiple dependent claims is withdrawn in view of Applicant's claim amendments.

Rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, for lacking enablement of "solvates" and of claims 2-4 for use of the term "characterized" are withdrawn in view of Applicant's claim amendments.

Rejection of claims 2-3 under 35 U.S.C. 112, second paragraph, as being indefinite on the grounds that the term "alkyl" lacks antecedent basis is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112, Second Paragraph

In the Non-Final Rejection, claim 12 was rejected as indefinite for recitation of the term "controlling" on the grounds that it was not clear whether one of skill in the art would interpret this claim to mean "prophylaxis", "alleviating symptoms" or "reducing viral growth".

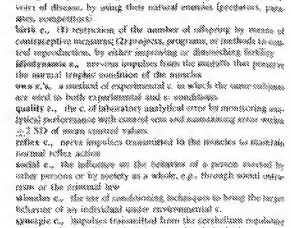
In the Reply, Applicant's argue that one of skill in the art would interpret "controlling" to mean reducing viral growth. However, Applicant provides no reasons why one of skill in the art would interpret this term in that manner. The term "controlling" is not defined or even once mentioned in the specification.

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int 'l, Inc. v. Cardinal Chem.* Co., 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

In the instant case, the Examiner does not find that the term "controlling" is used as a term of art with respect to administering pharmaceuticals. Does "controlling" relate to the particular patient treated or to stop the virus spread in a population or does it relate

to a virus vector (for example, administering the compound to an animal to control the spread of virus form the animal population to the human population)?

Stedman's Medical Dictionary gives the following definition.


control (kon-trol') [Moderne. L. contrarotulus, a counterroll for checking accounts, fr. L. contra, against, + rotulus, a roll] 1. To verify an experiment by means of another with the critical variable omitted. 2. A control animal or experiment. 3. The regulation of manifestations of a function, action, reflex, etc.
biological c., c. of living organisms, including vectors and transmitters of disease, by using their natural enemies (predators, parasites, competitors).
birth c., (1) restriction of the number of offspring by means of contraceptive measures; (2) projects, programs, or methods to control reproduction, by either increasing or diminishing fertility.
feedback c., nervous impulses from the muscles that preserve the normal tonic condition of the muscles.
gene c., a method of experimental c. in which the same subjects are used in both experimental and c. conditions.
quality c., the c. of laboratory analytical error by monitoring analytical performance with control sera and maintaining error within ±2 SD of mean control values.
reflex c., nerve impulses transmitted to the muscles to maintain normal reflex action.
social c., the influence on the behavior of a person exerted by other persons or by society as a whole, e.g., through social institutions or the criminal law.
stimulus c., the use of conditioning techniques to bring the target behavior of an individual under environmental c.
synaptic c., impulses transmitted from the cerebellum modulating the muscular activity of the synergic units of the body.
time-varied gain c., (TVGC), tone compensating gain; time-varied gain change in gain at different depths with time, to compensate for the decrease in echo amplitude from greater depths in ultrasonic applications.
tonic c., nerve impulses that maintain a normal tonus or level of activity in muscle or other effector organs.
vestibulo-equilibratory c., nerve impulses transmitted from the semicircular canals, saccules, and utricle that serve to maintain the equilibrium of the body.

See, STEDMAN'S MEDICAL DICTIONARY 348 (William R. Henzyl et al., eds, 25th ed., 1990). Stedman's definition does not convey the meaning Applicant seeks.

In view of the foregoing, the 35 USC § 112, second paragraph, rejection of claim 12 is maintained because the term "controlling" with respect administering a compound of formula I to control viral infections is ambiguous and therefore infinite.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 and 12 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling one of skill in the art to inhibit human cytomegalovirus (HCMV) by contacting HCMV with a compound of formula 1, does not reasonably enable one of skill in the art to practice a method for the treatment, prophylaxis (prevent or preventing) or control of viral infections as recited in claims 6-8 and 12.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims because the amount of experimentation for one of ordinary skill in the art to make and use Applicant's claimed method to prevent, treat or control viral infections generally by administering compounds from within the claimed genus is undue.

The Full Scope of Claims6-8 and 12 Are Not Enabled

The factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

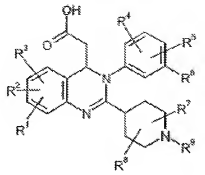
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); MPEP § 2164.01(a).

The Breadth of the Claims and Nature of the Invention

Nature of the Invention

Applicant's claims 6-8 relate to methods for preparing medicaments for prophylaxis and treatment of viral infections generally in humans and animals and claim 12 relates to a method of controlling viral infections in humans and animals with a compound of the following generic formula of claim 1:



(I),

wherein the variables are as defined in the body of claims.

Breadth of the Generic Formula of Compounds

The breadth of the claimed generic formula of compounds is quite broad in that it encompasses, conservatively, hundreds of thousands of different compounds, depending on assignment of variables.

Breadth of the Viral infections Treated

Applicant's claims are directed to treatment of viral infections in general. In contrast to mammalian cells or bacterial, fungal, or parasitic pathogens, viruses as a group do not share the same type of genome or the principle of its replication. B. Muller et al., *Antiviral Strategies in*, ANTIVIRAL STRATEGIES 1-24, 4 (H.-G. Krausslich et al., eds., 2009). Viral genomes can consist of single- or double-stranded DNA or RNA, viruses and are classified into seven groups according to the type of genome and the genome replication strategy: (I) Herpesviruses, Poxviruses, Papillomaviruses and Adenoviruses, (II) Parvovirus B19, (III) Rotavirus, (IV) HCV, Poliovirus, Rhinoviruses, Coronaviruses, and West-Nile-Virus, (V) Influenzavirus, Rabies Virus, Measles Virus, Respiratory, and Synctial Virus, (VI) HIV, Human T-cell, Leukemia Virus, and (VII) HBV. Id.

Furthermore, viruses can be naked (i.e., containing only a protein shell) or enveloped by a lipid membrane that surrounds the protein shell and is derived from a host cell membrane. Id. While double-stranded DNA viruses largely use cellular pathways for genome replication, RNA viruses, or viruses replicating in the cytoplasm, have to provide own enzymes to mediate their virus-specific replication strategies. Id. These enzymes represent targets for specific inhibition. Id.

It is further noted that the instant claims covers diseases or disorders caused by 'viral infection' due to viruses that are known to exist and those that may be discovered in the future, for which there is no enablement provided.

Furthermore, Applicant claims 6-8 are directed to methods for preparing medicaments for prophylaxis of viral infections. Thus, in addition, to treating and controlling viral infections, the subject claims require, at a minimum, that one of ordinary skill in the art identify those individuals likely to develop viral infections. Thus, to enable the full scope of the subject claims regarding "prophylaxis", one of skill in the art would require diagnostic methods to identify not only those afflicted with viral infections, but also those at risk of developing the many different viral types. Thus, the scope of patients and types and stages of antiviral infection as well as diagnostic methods necessary further broadens the claim scope of medicaments for prophylaxis of viral infections.

In view of the foregoing, the breadth of Applicant's claim with respect to prophylaxis, treatment and/or controlling of virus generally is very broad.

The State of the Art of Antiviral Drug Discovery and Its Unpredictability

The instant claims are directed to the unpredictable chemical and pharmaceutical arts, specifically, discovery and development of therapeutically active compounds.

The "scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Generally, in the pharmaceutical arts, identifying lead compounds from within a compound genus is a time consuming, unpredictable and expensive process. J.H. Poupaert, *Drug Design: Basic Principles and Applications, in* 2 ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY 1362-1369, 1367 (James Swarbrick ed., 3rd ed., 2007); *see also*, L.I. Zon et al., *Nature Reviews Drug Discovery* 4, 35 (2005). First target compounds must be identified (for example, by structure activity relationships), synthesized and then tested *in vitro* for activity against the target. *Id.* Typically, if only an *in vitro* model is available an *in vivo* model must be developed. L.I. Zon et al., *Nature Reviews Drug Discovery* 4, 35 (2005). Active compounds must then be subjected to a lengthy series of tests and evaluations, including toxicology, adsorption, distribution, pharmacokinetics and metabolism testing. *Id.*

High-throughput random screening of antivirals can be set up by defining a specific viral target (e.g., Virus-encoded enzymes) and establishing an in vitro assay appropriate to measure the function of this viral factor in the presence or absence of an inhibitor. B. Muller et al., *Antiviral Strategies in*, ANTIVIRAL STRATEGIES 1-24, 7 (H.-G. Krausslich et

al., eds., 2009). In vitro systems mimicking non-enzyme mediated steps in virus replication, for example, virus assembly or protein–protein interactions between viral and cellular factors, are also being developed. Id.

A fundamentally different approach is the procedure of rational antiviral drug design. Id. Starting from detailed information on the molecular structure and function of a specific viral target, substances expected to bind to this target and to interfere with its function are identified by computer-aided design and subsequently synthesized and tested for inhibitory action. Id. Again, suitable assay procedures to test for the inhibitory potential of in silico defined lead compounds have to be developed and the properties of the substance have to be improved by an iterative procedure. Id.

And treatment of viral infections not only depends upon virus type but also the particular stage of pathogenesis. For example, the treatment of established cytomegalovirus is extremely difficult since the virus may trigger pathological phenomena unresponsive to antiviral drugs and because extensive tissue damage is often followed by target organ failure and secondary opportunistic agents, which present their own management problems. P.D. Griffiths, *Cytomegalovirus in*, PRINCIPLES AND PRACTICE OF CLINICAL VIROLOGY 85-122 (A.J. Zuckerman et al., eds, 5th ed., 2001). No double-blind randomized placebo-controlled trial of anti-CMV therapy in established CMV disease has demonstrated that treatment at this late stage can provide a clinical benefit. *Id.*

In view of the foregoing, the art of identifying pharmaceutically useful antivirals is unpredictable. The patent courts have also recognized the unpredictability in the chemical arts. See e.g., I*n re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity); *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA1971) ("in the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim"); *In re Carleton*, 599 F.2d 1021 , 202 USPQ 165 (CCPA 1979) ("Although there is a vast amount of knowledge about general relationships in the chemical arts , chemistry is still largely empirical, and there is often great difficulty in predicting precisely how a given compound will behave.").

The art discussed and referred to above indicates that level of one of ordinary skill in the art holds a Ph.D. or MS in organic or medicinal chemistry and several years of industrial or academic experience in pharmaceutical or related research.

Guidance in the Specification

Applicant's specification contains no guidance regarding which species within the claimed genus are useful to prevent, treat and/or control specific viral types and stages. Broad dosage ranges are disclosed at p. 19, with no particular dosages disclosed for particular compound species or particular viral infections. Furthermore, Applicant presents no model that correlates the claimed compounds' ability to prevent, treat and/or control antiviral infections. While the specification discloses data for the HCMV inhibition of four example compounds, indicia of antiviral effectiveness in humans or animals is absent. *Current Application* at 52. Furthermore, Applicant's specification contains no teaching or evidence that the working examples relating to HCMV inhibition correlate with the compound's ability to treat an antiviral infection.

Essentially, the potency of the ligand toward the target (i.e. Ki, IC50 or related metrics) while predictive of good inhibitors, does not necessarily translate to a therapeutically useful drug. *See e.g.*, C. Abad-Zapatero, *Drug Discovery Today*, 1-8 (2010) (and references cited therein). And it is generally held that neither cell-based assays nor even xenograft models are particularly successful in predicting the efficacy of drugs humans. N.E. Sharpless et al., *Nature Reviews Drug Discovery* 1-14, 3 (2006).

Accordingly, one of skill in the art would not accept Applicant's HCMV inhibition studies as reasonably correlating to the compound's ability to prevent, treat or control a particular antiviral infection, let alone antiviral infections generally. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2164.02.

Regarding Applicant's claim to medicaments for prophylaxis of viral infections, Applicant provides no guidance in the specification regarding: (1) diagnostic methods to identify those at risk of developing viral infections, (2) which compounds of the invention are useful to prevent viral infections, (3) what types of viral infections are prevented by particular compounds of the invention, (4) dosages and treatment regimens to prevent viral infections.

Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art.

The Quantity of Experimentation Needed Is Undue

In the current case, Claims 6-8 and 12 are properly rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement because the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full claim scope without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); MPEP 2164.01(a); In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Regarding experimentation in drug discovery, generally, the first step is to identify a hit ligand and then screening a compound library against it. I. Collins, *Current Signal Transduction Therapy*, 1, 13-23, 13 (2006). However, this is just a starting point which must be followed by activity confirmation, biochemical characterization of the inhibitors and appropriate counter screens to rule out false positives. *Id.* at 14. Hits may also need to be disregarded for gross toxicological liabilities, such as chemically reactive functional groups or membership of known pharmacological classes. *Id.* Essentially, the potency of the ligand toward the target (i.e. Ki, IC50 or related metrics) while predictive of good inhibitors, does not necessarily translate to a therapeutically useful drug. *See e.g.*, C. Abad-Zapatero, *Drug Discovery Today*, 1-8 (2010) (and references cited therein).

Given the complex mechanism of disease, it is essential that potential drug candidates be tested in a model predictive of *in vivo* efficacy. N.E. Sharpless et al., *Nature Reviews Drug Discovery* 1-14, 2 (2006). The predictive model should reflect the natural history, pathobiology and biochemistry of the human disease. B. Hann *et al.*, *Current Opinion in Cell Biology*, 13, 778-784 (2001).

In the instant case, claims 6-8 and 12 are directed, conservatively, to hundreds of thousands of compounds and treatment of hundreds of viral infections. And as discussed above, the art of identifying antiviral compounds is unpredictable and difficult. Further Applicant has provided no working examples directed to preventing, treating and/or controlling antiviral infections in humans or animals or guidance as to which compounds within the claimed genus are suitable to treat particular antiviral infections. Applicant has disclosed no working model correlating the claimed compounds' HCMV inhibition activity with actual effectiveness in treating antiviral infections.

Screening for antivirals from compound libraries, such as Applicant's claimed genus, are not likely to identify a drug suited for treatment in the first round, but rather may yield lead compound(s) that have to be validated by alternative assay procedures and subsequently improved in potency and pharmacological properties by iterative cycles of chemical modification and testing. B. Muller et al., *Antiviral Strategies in*, ANTIVIRAL STRATEGIES 1-24, 7 (H.-G. Krausslich et al., eds., 2009). And the identification and

validation of antiviral targets, development of appropriate assays, and identification of lead compounds require considerable efforts from a team of scientists. Id.

Regarding Applicant's claims to medicaments for prophylaxis of viral infections, one of skill in the art would have to develop methods to identify those patients likely to develop viral infections generally. Such research and development would necessarily be extensive. And would require extensive and potentially open-ended clinical research on healthy subjects.

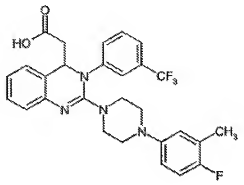
And even if it was argued that ordinary skill in the art could develop such general diagnostic methods, there still remains the fact that there are no known agents that "prevent" viral infections generally. There is thus substantial evidence that achieving such a goal is beyond the skill of the practitioners in that art. *Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1364, 42 USPQ2d 1001 (Fed. Cir. 1997) (the fact that no one had been able to produce any human protein via cleavable fusion expression as of application date of patent in suit undermines patentee's contention that specification's disclosure of DNA sequence encoding human growth hormone and single example enzyme and its cleavage site, without more, would have enabled one skilled in art to have used claimed cleavable fusion expression method to make hGH without undue experimentation"). Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished. See e.g., *In re Ferens*, 163 USPQ 609 (CCPA 1969).

In sum, Applicant's specification merely provides a starting point for further research and testing of the claimed compounds as potential antiviral agents for use in humans and animals. The amount of experimentation needed to enable the full scope of claims 6-8 and 12 is undue in view of Applicant's disclosure and rejection under 35 U.S.C. § 112, first paragraph, is appropriate.

Subject Matter Free of the Prior Art of Record

Compound and composition claims 1-4 and 9-10 are not anticipated by or rendered obvious in view of the prior art of record.

The closest prior art of record to claims 1-4 and 9-10 is T. Wunberg et al., WO 2004/072048 (Aug. 26, 2004) ("Wunberg"). At page 22, Wunberg discloses the compound of Example 1, depicted below.



Example 1, page 32

Wunberg Example 1 differs from the compounds of claims 1-3 and 9-10 because in comprises an 8-piperazine rather than an 8-piperidine substituted 3,4-dihydroquinazoline.

The closer the structural similarities between the claimed compounds and the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner. *In re Dillon*, 16 USPQ2d 1897, 1901 (Fed. Cir. 1996); *In re Merck & Co.*, 231 USPQ 375, 378-379 (Fed. Cir. 1986). But in order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on Applicant's disclosure or the mere fact that the components at issue are functional equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

In the instant case, one of skill in the art would not be motivated to modify Wunberg by replacing exchanging nitrogen for carbon (i.e., 8-piperazine → 8-piperidine substituted 3,4-dihydroquinazoline) because the prior art of record does not teach or suggest this modification.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to ALEXANDER R. PAGANO whose telephone number is (571)270-3764. The Examiner can normally be reached on Monday through Friday, 8:30 AM - 5:00 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALEXANDER R PAGANO

Examiner, Art Unit 1624

/JAMES O. WILSON/

Supervisory Patent Examiner, Art Unit 1624

ARP